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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/496,771	02/03/00	BELL S	37070/198653

023370
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EXAMINER	
ZEMAN,R	
ART UNIT	**PAPER NUMBER**
1645	7

DATE MAILED: 11/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/496,771	Applicant(s) Bell et al.
	Examiner Robert A. Zeman	Group Art Unit 1645

☒ Responsive to communication(s) filed on *Feb 3, 2000*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-77* is/are pending in the application.

Of the above, claim(s) *4-16, 19-39, 44-46, 51, 52, 54-56, 58-61, and 66-76* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-3, 17, 18, 40-43, 47-50, 53, 57, 62-65, and 77* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *6*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- *SEE OFFICE ACTION ON THE FOLLOWING PAGES* ---

DETAILED ACTION

Election/Restriction

Applicant's election of Group I, **with traverse**, in Paper No. 5 is acknowledged. Applicant's argument that the "presence of the claims of Groups I-VII does not impose an undue burden on examination since the features differentiating each group are merely further limitations of claim 1 has been fully considered and found not to be persuasive. Contrary to Applicant's assertion that each group represents a different species of the invention of claim 1, each group represents a patentably distinct invention. Each having differing chemical, biochemical and immunological properties and differing issues regarding enablement of said inventions. Additionally, each group would require a non-overlapping search.

Claims 1-3, 17, 18, 40-43, 47-50, 53, 57, 62-65 and 77 pending and currently under examination. Claims 4-16, 19-39, 44-46, 51-52, 54-56, 58-61 and 66-76 have been withdrawn from consideration.

Claim Objections

Claim 42 is objected to because of the following informalities: said claim must refer to preceding claims in the alternative only. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 17-18, 47-50, 53, 57 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 50, 53 and 57 are rendered vague and indefinite by the use of the term "partially coated". What percentage of the particle must be coated to be considered "partially coated" as opposed to "uncoated" or "coated". Additionally, must the coating equally dispersed over the particle or can it localized in a given region of the particle? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 17 recites improper Markush language. The use of an "or" and an "and" makes it impossible to determine whether the "peptides of a virus" is a separate group or grouped with "functional proteins".

Claim 47 is rendered vague and indefinite by the use of the term "reacting". Does Applicant mean the two salts are admixed or are other steps involved? If so what are they? As written it is impossible to determine the metes and bounds of the claimed invention.

Claim 53 is dependent on a nonelected claim. Claim 53 must be amended to incorporate all the limitations of the parent claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 17, 40-43, 47-48 53, 62-65 and 77 are rejected under 35 U.S.C. 102(b) as being anticipated by Relyveld (U.S. Patent 4,016, 252-- IDS-6).

The aforementioned claims are drawn to calcium phosphate particles with a diameter ranging from 300 nm to 4000 nm that are optionally coated (either partially or fully) with an antigenic material (viral in origin). Said particles are used in a vaccine composition comprising said particles and an pharmaceutically acceptable carrier or other expient. Claims are also drawn to methods of making said particles and methods of using said particles as a vaccine adjuvant.

Relyveld discloses an aqueous gel of calcium phosphate useful for preparation of adsorbed vaccines, prepared by contacting an antigen with the aqueous gel. Relyveld further discloses the methods for making said gel from calcium chloride and sodium phosphate (See example 1) and methods for making said gel in combination with viral vaccines (see examples 2-9) as an adjuvant. With regard to particle size, Relyveld discloses that his gel "exhibits a marked colloidal character. It is well known in the art that colloid is defined as "a

substance consisting of very tiny particles that are usually between 1 nm and 1000 nm in diameter and that are suspended in a continuous medium, such as a liquid, a solid, oar a gaseous substance" (Academic Press Dictionary of Science and Technology, Online edition, PTO-892). The aforementioned claims recite the limitations of "substantially smooth" and "substantially spherical". The above cited reference does not disclose these limitations *per se* but in the absence of factual evidence to the contrary, the prior art particles are deemed to anticipate the claimed particles because are disclosed particles of the same composition and the same size. Consequently, the Relyveld anticipates all the elements of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

t This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 17, 18, 40-43, 47-48 53, 62-65 and 77 rejected under 35 U.S.C. 103(a) as being unpatentable over Relyveld (U.S. Patent 4,016, 252-- IDS-6) in view of Kossovsky et al. (U.S Patent 5,462,750 -- IDS-6).

The aforementioned claims are drawn to calcium phosphate particles with a diameter ranging from 300 nm to 4000 nm that are optionally coated (either partially or fully) with an antigenic material (viral in origin). Said particles are used in a vaccine composition comprising said particles and an pharmaceutically acceptable carrier or other expient. Claims are also drawn to methods of making said particles and methods of using said particles as a vaccine adjuvant.

Relyveld discloses an aqueous gel of calcium phosphate useful for preparation of adsorbed vaccines, prepared by contacting an antigen with the aqueous gel. Relyveld further discloses the methods for making said gel from calcium chloride and sodium phosphate (See example 1) and methods for making said gel in combination with viral vaccines (see examples 2-9) as an adjuvant. With regard to particle size, Relyveld discloses that his gel "exhibits a marked colloidal character. It is well known in the art that colloid is defined as "a substance consisting of very tiny particles that are usually between 1 nm and 1000 nm in diameter and that are suspended in a continuous medium, such as a liquid, a solid, oar a gaseous substance" (Academic Press Dictionary of Science and Technology, Online edition, PTO-892). Relyveld differs from the claimed invention in that he does not disclose the use of EBV, HIV,

HPV, HSV, pox or influenza viral proteins as the previously described antigenic material. Kossovsky et al. disclose biologically active particles with diameters of less than 1000 nm which are coated with various viral proteins. Kossovsky et al further disclose that suitable sources for the viral proteins include EBV, HIV, HPV, HSV and pox viruses (see column 5, lines 54-58). Since the particles disclosed by Relyveld and Kossovsky et al. are similar with regard to size and function, it would have been obvious to use the viral proteins disclosed by Kossovsky et al. with the particles disclosed by Relyveld as to derive the benefit of the readsorbtive property of said particles.

Conclusion

No claim is allowed.

Claims 49-50 and 57 are free of the art of record. The art of record does not disclose a method of preparing calcium phosphate particles comprising the admixing of a calcium chloride solution and a sodium citrate solution with the subsequent addition a calcium phosphate solution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.

DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman

November 6, 2000